

Institutional Biosafety Committee - Regular Meeting

Thursday, March 05, 2026

Zoom

Meeting Minutes

VOTING MEMBERS PRESENT:	K. Burns, J. Corcoran, D. Elsaesser, M. Espinola, S. Kasper, E. Otten, E. Serafin, T. Rausch
VOTING MEMBERS NOT PRESENT:	S. Apewokin, G. Babcock, G. Dean, R. Larson, E. Otten, F. Schaefer, J. Yu
AD HOC MEMBERS/CONSULTANTS/GUESTS:	L. Elkin, M. Linke, J. Strasser
IBC STAFF:	D. Healy, B. Kesavalu

K. Burns convened the meeting at 12:00 p.m.

- I. **Conflicts of Interest** - No conflicts were identified.
- II. **Minutes** - Minutes from the previous IBC meeting (02/05/26) were approved 8: YES/0: NO/0: Abstained)
- III. **Old Business** – No old business to discuss

IV. New Business

A. Primary Protocols (2 protocols)

IBC Protocol Number	PI	Type of Submission	IBC Items	
1. 26-02-11-01	Zabeti	New Clinical	CAR-T cells (TRX319-01)	
IBC Requests:	<p><u>IBC Form</u></p> <ol style="list-style-type: none"> Section I - The IRB approval date provided is not from the UC IRB and the external IRB review is not approved, yet. Remove date; Section II. B - Define “PPMS” as it is used and then progressive MS is spelled out. Are they different?; Section II. B - Fix the symbols (boxes) that are after the IL1 and TNF; Section II. C. 1 - Gene Name - List the different genes (CAR, IL10 and truncated NGFR) separately and then complete the other columns accordingly; Section II. C. 2 - In “Additional Information”, indicate that virus is used to modify T cells to be given to patients; Section II. C. 4 - Indicate that “LVV” is "lentiviral vector"; Section II. C. 4 - For clarity, modify last sentence to read "Lentivirus transduced cells are to be..."; Section III. A - Location #1 - PPE to protect skin and face mucosa should be included while administering the IP. 			
Motion	Approve upon modifications addressing outlined issues.			
Voting Result & Dual Use	YES: 8	NO: 0	Abstained: 0	Dual Use? No

IBC Protocol Number	PI	Type of Submission	Biosafety Level	IBC Items
2. 25-05-23-01	Lewis	Amendment	BSL2	<i>in vitro</i> : gamma-retroviral vector, HDM (blood, serum, plasma, tissues) and <i>Escherichia coli</i> (RG1) <i>in vitro</i> and <i>in vivo</i> : HDM (established cell lines, including virally transduced cells) AMENDMENT: <i>in vitro</i> and <i>in vivo</i>: AAV vector
IBC Requests:	<p><u>Main Form – General Safety:</u></p> <ol style="list-style-type: none"> Section V - Be aware that alcohol-based disinfectants are not recommended for non-enveloped viruses (e.g. AAV). If those are used, they should be only for removing corrosive bleach residues from metallic surfaces. Check YES for "Additional Information" and include a statement in this regard. <p><u>Form A – Recombinant or Synthetic Nucleic Acid:</u></p> <ol style="list-style-type: none"> Section I - Gene #4 - "Gene Source" should be "arthropod"; Section II. B - System #2 - Human tropism should be YES. Also, the experimental approach and rationale (genome copy number, route of admin, expression strategy) is already stated elsewhere; it can be removed from this section. <p><u>Form D – Biohazard in Animals:</u></p> <ol style="list-style-type: none"> Section II - Animals receiving Viral Vectors should stay within the LAMS Biocontainment area for 72hr and then should be transferred to the LAMS Standard Housing area. Check the boxes to reflect this; Section II - In "Additional Information", indicate all routes of administration for viral vectors and cells. Form C describes implantation of transduced cells by pancreatic injection, orthotopic implant to mammary fat pad, tail vein, and intra-splenic injections. However, only retro-orbital and tail vein are mentioned in this form. Related to this, in Section III A it says retro-orbital and in Section III B it says tail vein for the same agents AAV8-asTF and hRabMab1. Clarify if one or both routes are used for systemic injection; Section III. B - Remove IACUC protocol number since it is already at the top of this form, and that way you won't have to change this every time the IACUC protocol is renewed. 			
Motion	Approve upon modifications addressing outlined issues.			
Voting Result & Dual Use	YES: 8	NO: 0	Abstained: 0	Dual Use? No

B. Secondary Protocols (4 protocols)

IBC Protocol Number	PI	Type of Submission	Biosafety Level	IBC Items
1. 26-02-06-01	Kotarsky	New	BSL2	<i>in vitro</i> : HDM (blood)
IBC Requests:	<p><u>Main Form – General Safety:</u></p> <ol style="list-style-type: none"> Section III. B - In "Additional Information", indicate what type of sharps are disposed of in sharps containers; 			

	<p>2. Section III. C - Whenever working in a lab, closed-toe shoes must be worn. Check the box in this regard.</p> <p>Form C – Human and NHP Derived Materials:</p> <p>3. Section I - Table: Include "species" info;</p> <p>4. Section I. A will appear when "human" is checked in Section I. Complete section accordingly.</p>			
Motion	Approve upon modifications addressing outlined issues.			
Voting Result & Dual Use	YES: 8	NO: 0	Abstained: 0	Dual Use? No

IBC Protocol Number	PI	Type of Submission	Biosafety Level	IBC Items
2. 26-02-22-01	Rodriguez-Molina	New	BSL1	<i>in vitro: Escherichia coli</i> (RG1: BL21), <i>Saccharomyces cerevisiae</i> , baculovirus
IBC Requests:	<p>1. PI has to complete BSC training;</p> <p>Main Form – General Safety:</p> <p>2. Section I. A and I. B - Enter the UC Mail code;</p> <p>3. Section I. B - If Secondary Contact does not have an office and lab does not have a number, enter "N/A" ;</p> <p>4. Section I. C - Provide phone number for authorized personnel;</p> <p>5. Section II. B - Correct the spelling for the yeast species (i.e. <i>cerevisiae</i>);</p> <p>6. Section III. B - Check YES for "Additional Information" and indicate which activities involving microorganisms need to be conducted inside of a fume hood. Uncheck box if the equipment is only used for chemicals;</p> <p>7. Section III. B - In "Additional Information", indicate what type of sharps are disposed of in sharps containers;</p> <p>8. Section III. C - Lab coats should be included in the PPE list. Check the box for that.</p> <p>Form A – Recombinant or Synthetic Nucleic Acid:</p> <p>9. Section II - Select "Viral vector" for baculovirus (remove info in "other" and uncheck that box). Then complete Section II. A and II. B that will appear once box is checked.</p> <p>10. Section III – Check box #7 to reflect work with baculovirus.</p> <p>Form B – Microbial/Infectious Agents</p> <p>11. Agent #1 - Risk Group - Since these strains of <i>E. coli</i> are not pathogenic, the "Risk Group" should be RG1.</p>			
Motion	Approve upon modifications addressing outlined issues.			
Voting Result & Dual Use	YES: 8	NO: 0	Abstained: 0	Dual Use? No

IBC Protocol Number	PI	Type of Submission	Biosafety Level	IBC Items	Reviewer
3. 26-02-20-01	Govil	Renewal	BSL2	<i>in vitro</i> : HDM (blood, kidney tissues)	Full IBC
IBC Requests:	<p><u>Main Form – General Safety:</u></p> <ol style="list-style-type: none"> Section I. B - If lab does not have a phone, enter "N/A"; Section III. C - Since this section is only for PPE, remove the info regarding "storage"; Section VIII - This section is reserved for materials that are not being used in ongoing (nor in the planned near future) research and ONLY being maintained in storage. Revise if necessary. <p><u>Form C – Human and NHP Derived Materials:</u></p> <ol style="list-style-type: none"> Section I. A - The IRB protocol provided is no longer active. Provide your current IRB number. 				
Motion	Approve upon modifications addressing outlined issues.				
Voting Result & Dual Use	YES: 8	NO: 0	Abstained: 0		Dual Use? No

IBC Protocol Number	PI	Type of Submission	Biosafety Level	IBC Items	
4. 26-02-20-02	Martin	Renewal	BSL2	<i>in vivo</i> : <i>Staphylococcus aureus</i>	
IBC Requests:	<p><u>Main Form – General Safety:</u></p> <ol style="list-style-type: none"> Section I. B - If lab does not have a phone, enter "N/A". <p><u>Form D – Biohazard in Animals:</u></p> <ol style="list-style-type: none"> Section I - Update your IACUC protocol number. 				
Motion	Approve upon modifications addressing outlined issues.				
Voting Result & Dual Use	YES: 8	NO: 0	Abstained: 0		Dual Use? No

V. Other New Business - Compliance Issues (M. Espinola):

1) Thompson T. - Viral vector work without IBC approval.

- During the annual lab inspection, the BSO learned that the lab was using lentiviral vector without IBC approval.
- PI mistakenly thought that lentiviral vector was included in his IBC approval and stated that he will submit an amendment to include viral vector work and staff will complete viral vector training. An emergency IBC meeting will be scheduled within 2 weeks.
- The NIH/OSP was informally notified about this oversight, and a formal incident form will be submitted once IBC approval is obtained.

2) Kovall - PPE

- During a routine lab inspection, a lab staff was observed wearing sandals.
- As this is a repeated finding, a safety violation warning was issued.
- The lab responded confirming that sandals will no longer be worn.
- BSO included a warning indicating that any future instances will result in formal reporting to department leadership.

VI. Protocol Updates - January 29th to February 26th (18 protocols)

1. IBC# 25-07-07-01 - PI: Hudock - Personnel
2. IBC# 25-07-07-01 - PI: Hertlein - Location, Personnel
3. IBC# 24-10-10-01 - PI: Gao - Personnel
4. IBC# 25-03-19-01 - PI: Owens - Personnel
5. IBC# 25-07-03-01 - PI: Natarajan - Location
6. IBC# 24-03-13-01 - PI: Shirokawa - Location
7. IBC# 23-07-20-02 - PI: Hite - Personnel
8. IBC# 25-03-19-01 - PI: Owens - Personnel
9. IBC# 24-01-22-01 - PI: Czyzyk--Krzaska - Personnel
10. IBC# 24-01-18-01 - PI: Ikegami (former Alquist) - PI Reassignment, Personnel
11. IBC# 25-04-18-01 - PI: Cunningham - Personnel
12. IBC# 24-09-09-01 - PI: Sasaki - Location
13. IBC# 24-01-20-02 - PI: Scaglioni - Personnel
14. IBC# 25-10-22-01 - PI: Ray - Personnel
15. IBC# 25-10-07-01 - PI: Guan - Personnel
16. IBC# 25-04-28-01 - PI: Zhang XT - Location, Personnel
17. IBC# 25-05-06-01 - PI: Madala - Personnel
18. IBC# 25-08-11-02 - PI: Fan G - Personnel

VII. Reports

- A. IBC/ BSO of (M. Espinola)

Lab accident - Czyzyk--Krzaska

- An injury involving a glass pipet occurred on 03/03/26.
- The material within the pipet did not involve recombinant or synthetic nucleic acid molecules. Therefore, the accident was not reportable to the NIH/OSP.
- BSO of will meet with the PI and involved staff to obtain details of the accident in order to determine the root cause of the accident and discuss safety precautions and alternatives to prevent future occurrences.

Primary Protocols Continued (1 protocol)

IBC Protocol Number	PI's Link	Type of Submission	IBC Items
2. 26-02-20-03	Sohal	New Clinical	Adenoviral vector and CAR T cells (disp-10-101)
Pre-Review Findings:	<p><u>IBC Form</u></p> <ol style="list-style-type: none"> 3. Section I. A - Provide the UC Campus Mail code; 4. Section I. A – Table 2 - Clinical staff have to complete their BBP training/provide transcript; 5. Section II. B - Expand description to include the population of the study and provide the rationale of using adenovirus/ide-cel combination for solid tumors; 6. Section II. C. 1 - Gene Name - Row 3 should read "Transmembrane dBCMA (TM dBCMA)"; 7. Section II. C. 1 - Regulatory Elements - Row 3 -Information should be limited to "Adenovirus Major Late Promoter, adenovirus polyA"; 8. Section II. C. 2 - The "viral" box should also be selected and in "Additional Information" state that Lentivirus transduced T cells are used for CAR and adenovirus used for dBCMA, IL18 and CXCL9; 9. Section III. C - Be aware that alcohol-based disinfectants are not recommended for non-enveloped viruses (e.g. Adenovirus - DV-10). A disinfectant with a broader spectrum should be used instead; 10. Section VI - Considering that the adenovirus used in this study is replication competent, discuss the possibility of infection of patient, close contacts and staff. 		

- The primary reviewer was not present, and M. Espinola briefly presented the protocol.
- All pre-review findings above will be forwarded to the primary reviewer for assessment.
- An Emergency meeting will be scheduled within two weeks to review this and Dr. Thompson's amendment (discussed at Other New Business).

VIII. Educational Materials/Updates

- A. **Adenoviral Inciting Antigen and Somatic Hypermethylation in VITT** N Engl J Med. February 2026
- B. **Krystal Biotech Announces RMAT Designation Granted by FDA to KB707 for the Treatment of Advanced or Metastatic Non-Small Cell Lung Cancer**; Source: Krystal Biotech, Inc. February 2026.

K. Burns adjourned the meeting at 12:56 p.m.

